Claim Rejections With Respect to the Bernstein Reference

The Examiner rejects claims 1-7, 11, 12, 18, 19, and 20 under 35 U.S.C. § 102(b) as anticipated by the disclosure of U.S. Pat. No. 4,770,853 to Bernstein. The Examiner asserts the Bernstein reference discloses a device for performing a rapid immunodiagnostic test for group A streptococci using a phage associated lysine enzyme, relying principally on the disclosure beginning on col. 5, line 55.

With respect to pending claims 11, 12, and 18-20, Applicants respectfully traverse. The group C phase associated lysine enzyme disclosed by the Bernstein reference in the example starting at col. 5, line 56 is not a bacteriophage as set forth in the rejected claims. Instead, the cited Bernstein example employs an enzyme which fragments and solubilizes the streptococci (see, e.g., line 57-58). The bacteriophage of the present invention are viruses that infect target bacteria and inject their nucleic acid into the bacteria. The bacteriophage do not appreciably fragment the host bacteria. The claimed devices achieve a detection of the bacteria, in part by detecting the presence of this interaction. (See, e.g., the specification at pages 4-5). Because the Bernstein reference fails to teach or disclose the use of bacteriophage in such detection mechanisms, Applicants respectfully assert rejected claims 11, 12 and 18-20 are patentable over its disclosure.

Claim Rejections With Respect to the Gombrich Reference

The Examiner rejects claims 1-3, 6, 7, and 10 under 35 U.S.C. § 102(b) as anticipated by the disclosure of U.S. Pat. No. 5,573,951 (Gombrich et al.). The Examiner argues the Gombrich reference discloses a multi-chambered blood culture assay device in which some of the chambers are separated by a seal which is breached by rotation.

Although Applicants have cancelled the rejected claims, Applicants offer the following comments with respect to application of the Gombrich reference to the newly presented claims. The Gombrich reference fails to teach a chamber construction where the chambers are separated by a seal which is activatable by rotation of the seal.

Version With Markings to Show Changes Made:

8 (amended). [The device of claim 7] A device comprising at least two chambers separated by an activatable seal wherein upon activation of the seal the two chambers are in communication, wherein at least one chamber comprises a biological assay reagent; wherein at least two of the chambers are separated by a seal that rotates upon activation; and wherein a first chamber includes bacteriophage, a second chamber includes an antiviral agent, and a third chamber includes bacterial helper cells.

28 (new). A device comprising at least two chambers separated by an activatable seal wherein upon activation of the seal the two chambers are in communication, wherein at least one chamber comprises a biological assay reagent, wherein the seal is activatable by application of pressure to an outside wall of the device, and wherein the device and the chambers have essentially the same cross-sectional shape.

29 (new). The device of claim 28 wherein at least one of the chambers includes a liquid substance.

30 (new). The device of claim 29 wherein upon activation of the seal the two chambers are in fluid communication.

31 (new). The device of claim 28 wherein at least one of the chambers includes a solid substance.

32 (new). The device of claim 31 wherein the solid substance is in the form of a powder.

33 (new). The device of claim 28 wherein the biological assay reagent comprises bacteriophage, bacterial helper cells, metabolic regulators, selective agents,

proteins, antibodies, enzyme substrates, antiviral agents, dyes, indicator chemistries, pigments, nutrients, or combinations thereof.

34 (new). The device of claim 28 comprising at least three chambers, wherein at least two of the chambers are separated by a seal that rotates upon activation.

35 (new). The device of claim 28 wherein activation of the seal comprises rotating the seal.

36 (new). A device comprising at least two chambers separated by an activatable seal wherein upon activation of the seal the two chambers are in communication, wherein at least one chamber comprises a biological assay reagent and wherein activation of the seal comprises rotating the seal.

37 (new). The device of claim 36 wherein at least one of the chambers includes a liquid substance.

38 (new). The device of claim 37 wherein upon activation of the seal the two chambers are in fluid communication.

39 (new). The device of claim 36 wherein at least one of the chambers includes a solid substance.

40 (new). The device of claim 39 wherein the solid substance is in the form of a powder.

41 (new). The device of claim 36 wherein the biological assay reagent comprises bacteriophage, bacterial helper cells, metabolic regulators, selective agents,

proteins, antibodies, enzyme substrates, antiviral agents, dyes, indicator chemistries, pigments, nutrients, or combinations thereof.

42 (new). The device of claim 36 comprising at least three chambers, wherein at least two of the chambers are separated by a seal that rotates upon activation.

Applicants direct the Examiner's attention to Figures 6-8 of the Gombrich reference. Gombrich discloses a device having rotating chambers, not a seal that is activatable by rotation of the seal (see, e.g., col.7 lines 28-53). Moveover the device depicted in Figures 6-8 employ curved, fixed walls 140 and 142 that cannot be characterized as a representing a seal activatable in the manner presently claimed.

In view of the arguments and amendments offered herein, Applicants respectfully submit that the Examiner's grounds for objection and rejection are overcome and respectfully solicit reconsideration and withdrawal of the rejections and allowance of the application.

Respectfully submitted,

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